Cyclo Therapeutics Announces Last Patient Last Visit in Phase 1/2 Trial Evaluating Trappsol® Cyclo™ for the Treatment of Niemann-Pick Disease Type C

- Topline results from Phase 1/2 study on track for March 2021

- Individual and cumulative data seen to-date show Trappsol® Cyclo™ to be well tolerated with a favorable safety profile for all dose groups and to have encouraging signals in efficacy

- Pivotal Phase 3 study evaluating Trappsol® Cyclo™ for the treatment of NPC expected to commence enrollment in Q2 2021

Gainesville, FL – (Businesswire) – March 4, 2021 -- Cyclo Therapeutics, Inc. (Nasdaq: CYTH) ("Cyclo Therapeutics" or the "Company"), a clinical stage biotechnology company dedicated to developing life-changing medicines through science and innovation for patients and families suffering from disease, today announced that the last patient completed their last visit in the Phase 1/2 study evaluating Trappsol® Cyclo™, a proprietary formulation of hydroxypropyl beta cyclodextrin, administered intravenously (IV) to Niemann-Pick Disease Type C1 (NPC1) patients. The Company expects to report topline data for the Phase 1/2 study in March 2021.

NPC1 is a rare genetic disease affecting 1 in 100,000 live births globally. NPC affects every cell in the body due to a defect in the NPC1 protein which is responsible for cholesterol processing in the cell. As cholesterol accumulates in cells, NPC causes symptoms in the brain, liver, spleen, lung and other organs and often leads to premature death. There are no approved drug therapies for NPC in the United States and only one approved therapy in Europe.

"On behalf of Cyclo Therapeutics, I would like to express our sincere gratitude for all the patients, families and physicians who participated in this important study. We have been encouraged by the safety and efficacy data seen to-date and look forward to reporting topline data in the coming weeks," commented Sharon Hrynkow PhD, Chief Scientific Officer and Senior Vice President for Medical Affairs.

The randomized, double-blind Phase 1/2 study of Trappsol® Cyclo™ enrolled 12 patients aged 2 and above. Trappsol® Cyclo™ was evaluated in 3 dose groups (1500, 2000, 2500 mg/kg body weight) administered IV in NPC patients aged 2-plus bi-weekly over 48 weeks. To-date, individual and cumulative safety data show the drug to be well tolerated with a favorable safety profile for all dose groups.

Previously reported data from interim analyses show effects of IV drug administration on markers of cholesterol synthesis and metabolism, indicating clearance of cholesterol from cells. Pharmacokinetic data show the drug in cerebrospinal fluid during and even after the end of IV infusion, at all dose levels. Lysosphingomyelin-509 in plasma demonstrates a clear downward trend over the 48-week study, with no apparent dose-relationship, further supporting the drug's ability to clear lipids from cells. Tau, a biomarker of neurodegeneration, is reduced in cerebrospinal fluid of patients who opted for lumbar punctures at 24 and 48 weeks, suggesting a neuroprotective effect of the drug. For the 7 patients who completed the trial as of September 2020, 6 (86%) met the first efficacy criterion of the study related to improvement in 2 domains of the 17-domain Severity Scale. For the second efficacy outcome measure, change from baseline in global impression of disease, 5 of 7 patients improved per the Clinicians Global Impression of Improvement scale and 2 were stabilized.

Following review of the Phase 1 and Phase 1/2 data, coupled with preclinical and compassionate use data, regulatory authorities acknowledged that IV Trappsol® Cyclo™ has the potential to treat systemic and neurologic manifestations of NPC. Additionally, the European Medicines Paediatric Committee (EMA PDCO) noted Trappsol® Cyclo™ may have the capacity when given intravenously to be a preventative treatment. The Company has confirmation that the pivotal Phase 3 study may begin enrollment, which is expected to commence in Q2 2021.

For more information about the Phase 1/2 study, visit clinicaltrials.gov and reference NCT02912793.

About Cyclo Therapeutics

Cyclo Therapeutics, Inc. is a clinical-stage biotechnology company dedicated to developing life-changing medicines through science and innovation for patients and families suffering from disease. The Company's Trappsol® Cyclo™, an orphan drug designated product in the United States and Europe, is the subject of three ongoing formal clinical trials for Niemann-Pick Disease Type C, a rare and fatal genetic disease, (ClinicalTrials.gov NCT02939547, NCT02912793 and NCT02912793). The company is planning an early phase clinical trial using Trappsol® Cyclo™ intravenously in Alzheimer's Disease based on encouraging data from an Expanded Access program for late-onset Alzheimer's Disease (NCT03624842). Additional indications for the active ingredient in Trappsol® Cyclo™ are in development. For additional information, visit the company's website: www.cyclotherapeutics.com.

Safe Harbor Statement

This press release contains "forward-looking statements" about the company's current expectations about future results, performance, prospects and opportunities, including, without limitation, statements regarding the satisfaction of closing conditions relating to the offering and the anticipated use of proceeds from the offering. Statements that are

not historical facts, such as “anticipates,” “believes” and “expects” or similar expressions, are forward-looking statements. These statements are subject to a number of risks, uncertainties and other factors that could cause actual results in future periods to differ materially from what is expressed in, or implied by, these statements. The factors which may influence the company’s future performance include the company’s ability to obtain additional capital to expand operations as planned, success in achieving regulatory approval for clinical protocols, enrollment of adequate numbers of patients in clinical trials, unforeseen difficulties in showing efficacy of the company’s biopharmaceutical products, success in attracting additional customers and profitable contracts, and regulatory risks associated with producing pharmaceutical grade and food products. These and other risk factors are described from time to time in the company’s filings with the Securities and Exchange Commission, including, but not limited to, the company’s reports on Forms 10-K and 10-Q. Unless required by law, the company assumes no obligation to update or revise any forward-looking statements as a result of new information or future events.

Investor Contact:
JTC Team, LLC
Jenene Thomas
(833) 475-8247
CYTH@jtcir.com